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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/627,275

07/25/2003

Silvia Bertuglia

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O'MELVENY & MYERS LLP
610 NEWPORT CENTER DRIVE
17TH FLOOR
NEWPORT BEACH, CA 92660

EXAMINER

CWERN, JONATHAN

ART UNIT

PAPER NUMBER

3737

MAIL DATE

DELIVERY MODE

08/23/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/627,275	Applicant(s) BERTUGLIA, SILVIA	
	Examiner Jonathan G. Cwern	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 10-26, 28 and 38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 10-26, 28 and 38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10/23/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on 10/23/03 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1, 10-26, 28, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alexandrov et al. (US 6733450) in view of Horzewski et al.

Alexandrov shows the invention substantially, in the drawings and text as: with respect to claims 1, 10-26, 28, and 38, selecting a patient having a tissue with comprised microvascular perfusion (column 3, lines 45-65), the tissue being cerebral tissue (column 3, lines 45-65), applying an ultrasound transducer near the tissue

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(column 3, lines 45-65), activating the transducer to initiate exposure to ultrasound at a frequency of 100 KHz to 2.5 MHz (this covers all claimed frequency ranges, column 3, lines 45-65) for a duration of 0.5 to 15 minutes (this covers all claimed time periods, column 3, lines 45-65); applying gel to enhance transmission of ultrasound waves (column 6, lines 55-60); adjusting the focal length of ultrasound waves (column 4, lines 20-50); confirming the establishment of reperfusion (column 8, lines 45-65); injecting an anticlotting agent into the patient (TPA infusion, column 8, lines 45-50); ultrasound with a temporal and spatial average energy level of 0.01 to 1.00 watts/cm² (column 3, lines 45-65); and ultrasound with pulsed modulation (column 4, lines 20-50).

Alexandrov fails to show, with respect to claims 1, 10-26, 28, and 38, the compromised tissue being myocardial tissue; the compromised tissue being transplanted tissue; the patient experiencing a myocardial infarction; applying a portable ultrasound transducer within 30 minutes after ischemic injury to the site of the ischemic injury; wherein local vasodilation is stimulated.

Horzewski teaches, with respect to claims 1, 10-26, 28, and 38, the compromised tissue being myocardial tissue ([0005]); the compromised tissue being transplanted tissue ([0005]); the patient experiencing a myocardial infarction ([0004]); applying a portable ultrasound transducer within 30 minutes after ischemic injury to the site of the ischemic injury (because this device is portable, it can be used outside of a hospital, for example even in a person's home, or in a public setting, this allows a user to begin treatment immediately once a myocardial infarction occurs, within 30 minutes, and the

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portable device will provide treatment while the person is transported to a hospital, [0024]-[0028]); wherein local vasodilation is stimulated ([0024]).

Alexandrov focuses on cerebral tissue in his specification because of its difficulty, however this technique could be used in any ischemic tissue (column 1, lines 15-32). Horzewski teaches the specifics of using it on myocardial tissue and transplanted tissue. It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have used the device on any ischemic tissue, with the motivation that ischemic tissue can lead to severe complications for the patient, including death, and so it would be desirable to treat any ischemic tissue.

Alexandrov does not specifically mention vasodilation, dilating the blood vessels, however he describes stimulating perfusion in many similar ways, such as thrombolysis, reducing edema, promoting microcirculation, recanalization, increasing collateralized interstitial flow, and delivery of lytic agents, by using low frequency, low power ultrasound (abstract). All of these will serve to reperfuse the ischemic tissue. Horzewski specifically teaches that vasodilation will occur when using low power, low frequency ultrasound. It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have used low power, low frequency ultrasound to stimulate vasodilation, with the motivation that the phenomenon of vasodilation (dilation of the blood vessels) will allow reperfusion in the ischemic tissue as well.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have made the device portable as taught by Horzewski, in the device of Alexandrov, with the motivation that a portable device will allow treatment to

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the ischemic tissue to begin immediately, rather than waiting for the patient to be transported to a hospital in which time it could be too late to save the patient, preventing serious injury or death from occurring.

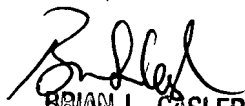
Conclusion

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See attached Notices of References Cited sheet.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan G. Cwern whose telephone number is 571-270-1560. The examiner can normally be reached on Monday through Friday 9:30AM - 6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

JC
8/4/07